

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
J. Vernon Knight et al.

Serial No.: 10/663,573

Filed: September 16, 2003

For: SMALL PARTICLE LIPOSOME
AEROSOLS FOR DELIVERY OF ANTI-
CANCER DRUGS

Group Art Unit: 1615

Examiner: Unknown

Atty. Dkt. No.: CLFR:158US

CERTIFICATE OF ELECTRONIC SUBMISSION

DATE OF SUBMISSION: September 18, 2008

INFORMATION DISCLOSURE STATEMENT

MS AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

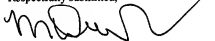
In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/CLFR:158US.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



Monica A. De La Paz
Reg. No. 54,662
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
(512) 474-5201

Date: September 18, 2006

Form PTO-1449 (modified)		Atty. Docket No. CLFR:158US	Serial No. 10/663,573
List of Patents and Publications for Applicant's		Applicant J. Vernon Knight <i>et al.</i>	
INFORMATION DISCLOSURE STATEMENT			
(Use several sheets if necessary)			
Filing Date: September 16, 2003		Group: 1615	
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1</i>	Other Art <i>See Page 1</i>	

U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	5,049,388	11/17/91	Knight <i>et al.</i>	424	450	07/21/89
	A2	5,422,344	06/06/95	Priel <i>et al.</i>	514	50	05/08/90
	A3	5,552,156	11/03/96	Burke	424	450	03/22/95
	A4	5,736,156	04/07/98	Burke	424	450	04/12/96
	A5	5,958,378	11/28/99	Waldrep <i>et al.</i>	424	45	10/16/96
	A6	6,090,407	07/18/00	Knight <i>et al.</i>	424	450	11/23/97
	A7	6,346,233	02/12/02	Knight <i>et al.</i>	424	45	07/17/00

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Language
	B1	DE 4430593C2	08/20/94	Germany	Abstract
	B2	WO 9318751	03/23/93	WIPO	English
	B3	WO 9426253	05/16/94	WIPO	English
	B4	WO 9605821	08/18/95	WIPO	Abstract
	B5	WO 9619199	12/20/95	WIPO	English

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	"Chiron submits new drug application for pulmini; inhaled form of cyclosporine could be first immunosuppressant indicated for chronic lung-transplant rejection," www.drugs.com/nda/pulmini_041014.html .
	C2	Abang <i>et al.</i> , "The clinical pharmacology of topoisomerase I inhibitors," <i>Sem Hematol</i> , 35:13-21, 1998.

25695214.1

EXAMINER:
DATE CONSIDERED:

EXAMINER. INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Form PTO-1449 (modified)		Atty. Docket No. CLFR:158US	Serial No. 10/663,573
List of Patents and Publications for Applicant's		Applicant J. Vernon Knight <i>et al.</i>	
INFORMATION DISCLOSURE STATEMENT		Filing Date: September 16, 2003	Group: 1615
(Use several sheets if necessary)			
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1</i>	Other Art <i>See Page 1</i>	

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C3	Ahmed <i>et al.</i> , "Influence of route of administration on [3h]-camptothecin distribution and tumor uptake in C57BL/6J nude mice: whole-body autoradiographic studies," <i>Cancer Chemother Pharmacol.</i> , 39:122-130, 1996.
	C4	Anderson, "Delivery systems for immunomodulatory proteins and peptides," <i>BioDrugs</i> , 7:51-65, 1997.
	C5	Burckart <i>et al.</i> , "Lung deposition and pharmacokinetics of cyclosporine after aerosolization in lung transplant patients," <i>Pharmaceutical Research</i> , 20:252-256, 2003.
	C6	Chourpa <i>et al.</i> , "Modulation in kinetics of lactone ring hydrolysis of camptothecins upon interaction with topoisomerase I cleavage sites on DNA," <i>Biochem.</i> , 37:7284-7291, 1998.
	C7	Fresta <i>et al.</i> , "Evaluation and optimization of liposomes as delivery device for methotrexate," <i>Pharmazie</i> , 47:926-929, 1992.
	C8	Garcia-Carbonero <i>et al.</i> , "Current perspectives on the clinical experience, pharmacology, and continued development of the camptothecins," <i>Clin. Cancer Res.</i> , 8:641-661, 2002.
	C9	Giovannella <i>et al.</i> , "Complete growth inhibition of human cancer xenografts in nude mice by treatment with 20-(S)-camptothecin," <i>Cancer Res.</i> , 51:3052-3055, 1991.
	C10	Hallman <i>et al.</i> , "Inositol supplementation in premature infants with respiratory distress syndrome," <i>N. Eng. J. Med.</i> , 326:1233-1239, 1992.
	C11	Hausheer <i>et al.</i> , "Kareneitcins: a novel, potent class of oral highly lipophilic topo I inhibitors," <i>Proc. Annu. Meet. Am. Assoc. Cancer Res.</i> , 38:A1526, 1997.
	C12	Hertzberg <i>et al.</i> , "Modification of the hydroxy lactone ring of camptothecin: inhibition of mammalian topoisomerase I and biological activity," <i>J. Medic. Chem.</i> , 32:715-720, 1989.
	C13	Hochster <i>et al.</i> , "Phase I trial of low-dose continuous topotecan infusion in patients with cancer: an active and well-tolerated regimen," <i>J. Clin. Oncol.</i> , 12:553-559, 1994.
	C14	Iacono <i>et al.</i> , "Aerosol cyclosporin therapy in lung transplant recipients with bronchiolitis obliterans," <i>Eur. Respir. J.</i> , 23:384-390, 2004.
	C15	Kim <i>et al.</i> , "Pharmacodynamics of insulin in polyethylene glycol-coated liposomes," <i>Int. J. Pharm.</i> , 180:75-81, 1999.
	C16	Knight <i>et al.</i> , "New approaches in aerosol drug delivery for the treatment of asthma," in <i>Allergy and Allergic Diseases</i> , Kay (ed), Blackwell Publications, Oxford, England, 1:730-741.

25695214.1

EXAMINER:

DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609, DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Form PTO-1449 (modified)		Atty. Docket No. CLFR:158US	Serial No. 10/663,573
List of Patents and Publications for Applicant's		Applicant J. Vernon Knight <i>et al.</i>	
INFORMATION DISCLOSURE STATEMENT		Filing Date: September 16, 2003	Group: 1615
(Use several sheets if necessary)			
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1</i>	Other Art <i>See Page 1</i>	

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C17	Lesueur-Ginot <i>et al.</i> , "Homocamptothecin, an E-ring modified camptothecin with enhanced lactone stability, retains topoisomerase I-targeted activity and antitumor properties," <i>Cancer Res.</i> , 59:2939-2943, 1999.
	C18	Mi <i>et al.</i> , "Reduced albumin binding promotes the stability and activity of topotecan in human blood," <i>Biochemistry</i> , 34:13722-13728, 1998.
	C19	Ozer, "Stability studies of 5-FU liposomes," <i>Drug Targeting Delivery</i> , 1:151-160, 1992.
	C20	Schreier <i>et al.</i> , "Pulmonary delivery of liposomes," <i>J. Controlled Release</i> , 24:209-223, 1993.
	C21	Sugarman <i>et al.</i> , "Lipid-complexed camptothecin: formulation and initial biodistribution and antitumor activity studies," <i>Cancer Chemother Pharmacol.</i> , 37:531-538, 1996.
	C22	Verschraegen <i>et al.</i> , "A phase I clinical and pharmacological study of oral 9-nitrocamptothecin, a novel water-insoluble topoisomerase I inhibitor," <i>Anti-Cancer Drugs</i> , 9:36-44, 1998.
	C23	Verschraegen <i>et al.</i> , "Alternative administration of camptothecin analogues," <i>Ann NY Acad. Sciences</i> , 922:237-246, 2000.
	C24	Waldrep <i>et al.</i> , "Cyclosporin A liposome aerosol: particle size and calculated respiratory deposition," <i>Int. J. Pharmaceutics</i> , 97:205-212, 1993.
	C25	Waldrep <i>et al.</i> , "Nebulized glucocorticoids in liposomes: aerosol characteristics and human dose estimates," <i>J. Aerosol Med.</i> , 7:133-145, 1994.
	C26	Weibel, "Geometry and dimensions of airways of conductive and transitory zones," In <i>Morphometry of the Human Lungs</i> , NY: Academic Press Inc., 110-140, 1963.
	C27	Zamboni <i>et al.</i> , "Phase I and pharmacokinetic (PK) study of intermittently administered 9-nitrocamptothecin (9NC, Rubitecan) in patients with advanced malignancies," <i>Proc. Am. Soc. Clin. Oncol.</i> , A411, 2001.

25695214.1

EXAMINER:**DATE CONSIDERED:**

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPPE609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.